UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

SUPPRESSED

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	NO.
	)	
JAMES R. NEWCOMB,	)	4:12CR00009 RWS
SANDRA L. BEHE, and	)	
ABID S. NISAR,	)	
	)	
Defendants.	)	

INDICTMENT

The Defendants

At all times relevant to this Indictment:

1. Defendant James R. Newcomb ("Newcomb") was a resident of California. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

2. Defendant Sandy Behe ("Behe") was a resident of California. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

3. Defendant Abid S. Nisar ("Nisar") was a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri and other Districts, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

4. Nisar was a licensed medical doctor who specialized in the treatment of patients with various types of cancer. Nisar operated offices in Florissant, Missouri, East St. Louis, Illinois, and Granite City, Illinois, where he treated residents of Missouri and Illinois. As part of his chemotherapy treatment of patients in Missouri and Illinois, Nisar purchased large amounts of assorted prescription drugs from businesses associated with Newcomb, Behe, and others, prescribed and dispensed these prescription drugs to his patients, and sought reimbursement for the drugs and their infusion from the Medicare and Medicaid programs, among other payors.

The U.S. Food and Drug Administration

5. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumers to use them in a safe manner and that drugs were listed by and

manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

6. Under the FDCA, anyone manufacturing, preparing, compounding, or processing prescription drugs for sale and use in the United States must annually register with the FDA as a drug establishment, and provide a list to FDA of the drugs which are being manufactured for commercial distribution. 21 U.S.C. §§ 360(a)(1), 360(j). The FDCA's registration requirement applies to both businesses located within the United States, and drug establishments outside of the United States that import their drugs into the United States. 21 U.S.C. §§ 360(b), 360(i). Any drug establishment, located within or outside of the United States, may be inspected by FDA or officials of foreign governments that act cooperatively with FDA. 21 U.S.C. §§ 360(h), 360(i)(3).

Prescription Drugs

7. Under the FDCA, drugs included: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, articles intended to affect the structure or any function of the body of man, and "biological products" applicable to the prevention, treatment, or cure of a disease or condition of human beings. 21 U.S.C. § 321(g)(1)(B) and (c); 42 U.S.C. § 262(i).

8. Under the FDCA a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

9. The drugs listed below, using the names under which the drugs are marketed in the United States, are used primarily to treat individuals with cancer, and are often "infused" into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients. All of these drugs were "prescription drugs" pursuant to 21 U.S.C. § 353(b)(1) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs:

Neupogen®
Herceptin®
Rituxan®
Gemzar®
Taxotere®
Eloxatin®
Zometa®
Venofer®

Misbranding

10. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is misbranded under the FDCA unless the labeling bore adequate directions for use. 21 U.S.C. § 352(f). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. All words, statements, and other information required to appear on drug labeling by the FDCA must be in the English language, unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(1). A drug is also "misbranded" if it was manufactured, prepared, propagated, compounded, and processed in any establishment in any state not duly registered with FDA. 21 U.S.C. § 352(o). Finally, any drug is misbranded if it came from a domestic or foreign drug establishment and that drug was not annually

listed with the FDA by the establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment. 21 U.S.C. §§ 352(o), 360(j).

Adulteration

11. A drug was "adulterated" if the drug and the methods used in, or the facilities or controls used for its manufacturing, processing, packing, and holding do not conform with current good manufacturing practices ("cGMP") to assure that the drug is safe and has the identity and strength and meets quality and purity characteristics which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

Misbranded Drugs In Missouri

12. Sometime in January 2010, a nurse employed by Nisar received a fax transmission at one of Nisar's offices from a business associated with defendants Newcomb, Behe, and others offering low prices on cancer chemotherapy prescription drugs. Nisar and his nurse discussed the possibility of buying cheaper prescription drugs, and contacted the business.

13. On or about February 8, 2010, Nisar received some marketing materials regarding assorted prescription drugs that are often used for cancer treatment, typically through intravenous infusion into the cancer patients' bodies as part of chemotherapy. These promotional materials informed Nisar that the prescription drug price list and materials were provided to him only on a "confidential basis." The forwarding or distribution of these materials was "strictly prohibited." Nisar also received an "actual oncology practice savings summary" suggesting that oncologists could purchase assorted prescription drugs at 14% – 60% off their average wholesale price in the United States, thereby saving practices an average of ".40 cents on every dollar spent on oncology medications." The cover letter informed Nisar that drug purchases "were best used to supplement

the medication purchases for medical practices, not in lieu of traditional wholesalers," as the "best way" to utilize these services was to purchase just a percentage of medications from defendants while using "your current wholesaler(s) for all other medications." The materials also provided a "frequently asked questions" section which stated that the drug seller was a licensed wholesaler in the United Kingdom and listed the numbers for two United Kingdom drug wholesaler licenses. However, the two licenses listed in this section were only for veterinary drugs, not human drugs.

14. Nisar began regularly purchasing prescription drugs from defendants Newcomb, Behe, and others during February through December of 2010. Nisar used his personal credit card to fund these drug transactions. The drug prices were substantially cheaper than what was offered by Nisar's legitimate U.S. based wholesale drug distributor. For example, a 10 syringe/480 milligram package of Neupogen® cost approximately $3,498 when purchased from the legitimate distributor in the United States, but cost approximately $1,050 when purchased from Newcomb and Behe's business.

15. At Nisar's request, prescription drug packages were shipped from overseas to his offices in Illinois and Missouri. Nisar then provided the drugs to his patients without informing them of the source of the drugs. After Nisar provided the drugs to his patients, Nisar submitted claims for reimbursement for these drugs to various health care benefit programs, including the Medicare program and the Medicaid programs of both Missouri and Illinois, without informing the programs of the source of the drugs. Nisar received reimbursement from the health care programs and also collected co-payments from beneficiaries for the drugs. Ultimately, Nisar purchased approximately $352,504 worth of prescription drugs from unlicensed foreign distributors through approximately 47 separate shipments containing 1,138 separate drug units.

16. The exterior packaging for Nisar's prescription drug shipments falsely described the contents of these packages as medical samples. Further, the customs declarations for these prescription drug shipments claimed that the monetary value of the packages was low, for example $10 or $50, when Nisar's acquisition cost for each drug package was typically between $2,000 and $12,000. Nisar also purchased prescription drugs from another source, and this source labeled imported drug packages as "gifts," sometimes providing no return address on the imported drug packages.

17. The labeling for the prescription drugs purchased by Nisar was different than the versions of these drugs that had been approved for sale in the United States by the FDA. For example, some of the labeling for some of the drugs from Newcomb and Behe was in foreign languages. Other drugs' labeling did not provide dosage information, or express the potency of the drugs in a standard format. 21 C.F.R. §§ 201.56, 610.61(n), (r). None of the drugs purchased by Nisar came from registered drug establishments, were annually listed as drugs being produced at registered drug establishments, or contained National Drug Codes.

18. All of the prescription drug Rituximab (marketed in the United States as Rituxan®) ordered by Nisar through the business where Newcomb and Behe worked was labeled "Mabthera." The labeling for the Rituximab obtained by Nisar says that this drug came from an unregistered drug establishment located in Switzerland that did not provide FDA with an annual list of any drugs manufactured there, and was distributed after manufacturing by another company located in New Delhi, India. By contrast, the FDA-approved version of Rituximab that is made for legal use in the United States is labeled "Rituxan®." Rituxan® is manufactured in a registered drug establishment in Vacaville, California. This drug establishment annually lists the drug Rituxan® with the FDA as

a drug that it is manufacturing at that facility. The FDA can also routinely inspect that California-based drug establishment.

Defendant Newcomb and Behe's activities

19. Defendants Newcomb and Behe were both employed at Ban Dune Marketing Inc. (BDMI"). From on or about January 1, 2008 through on or about May 18, 2011, defendant and others caused the distribution of prescription drugs from foreign countries to physicians located in the United States, including but not limited to Nisar, with the assistance of persons in Canada and the United Kingdom. These prescription drugs were not the U.S. version of these drugs that the U.S. Food and Drug Administration had approved for use in the United States, and their labeling did not contain NDC codes and other information from the U.S. labeling for these drugs.

20. During Fall 2010, Newcomb and Behe and others began causing the distribution into interstate commerce of what they called "cold chain" drugs, namely prescription drugs that require a uniform cold temperature during shipment. Some "cold chain" drugs had high profit margins, for example 30% or 52%. As an example of a "cold chain" drug, Neupogen® is a prescription drug that is typically intravenously infused into cancer patients. The U.S. labeling for this drug requires storage of the drug in a refrigerator at 2° to 8°C (36° to 46°F), and cautions that the drug should not be shaken. According to the U.S. labeling for this drug, if it is left at room temperature for longer than 24 hours, it should be discarded and not used with patients. Also, the FDA-approved U.S. labeling for the prescription drugs Herceptin® and Rituxan® requires that these drugs be kept at a constant temperature between 36 and 46 degrees Fahrenheit, and not shaken or frozen.

21. In Fall 2010, a number of doctors in the United States, including Nisar, began purchasing Neupogen® and other "cold chain" drugs from Newcomb, Behe, and others, along with other cancer treatment prescription drugs.

22. On or about October 13, 2010, Newcomb and Behe learned that Nisar had received a shipment of the prescription drugs marketed in the United States as Rituxan® and Herceptin® through BDMI. Newcomb and Behe and others were informed that when this drug package arrived at the offices of Nisar after being imported from outside the United States, it contained what a Missouri nurse described as "a gooey mess." A "gooey substance" covered two prescription drug boxes from this package, as one of the "cold packs" included in the box leaked or was damaged during shipment, making the boxes of the prescription drugs in the package wet and disintegrated. Newcomb and Behe and others provided a credit to defendant Nisar, recognizing these drugs could not be used on patients because of the lack of temperature control during shipment of these drugs.

23. After being notified of "cold chain" shipping problems, Newcomb became concerned about how much money would be lost if more "cold chain" products were delivered to U.S. doctors in a warm condition, as purchasers would likely demand credits, refunds, and replacement shipments of new drugs that did not have obvious "cold chain" problems. Having drug packagers place a thermometer inside drug packages that would be sent to U.S. customers so that the temperature would be recorded and shown to the U.S. physicians when the drugs arrived at their respective offices was considered as a shipping method. However, Newcomb abandoned the "thermometer in a box" concept, and concluded that "we mutually think adding a thermometer will be opening Pandoras Box if the temp dips and the thermometer shows that we will for certainly be eating a whole bunch of product - for discussion."

COUNT 1 - CONSPIRACY

The Conspiracy and its Objects

24. Paragraphs 1 through 23 are re-alleged and incorporated by reference as though fully set forth herein.

25. From on or about September 1, 2010 through on or about May 18, 2011, in the Eastern Division of the Eastern District of Missouri and elsewhere, defendant

JAMES R. NEWCOMB

and others, known and unknown to the Grand Jury, knowingly and willfully conspired and agreed together to commit an offense against the United States, to wit:

(a) to cause the introduction and delivery for introduction into interstate commerce quantities of prescription drugs, including the drugs marketed in the United States as Neupogen®, Herceptin®, and Rituxan®, that were adulterated in that the methods of their storage and shipment were not appropriate and did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of these prescription drugs, including maintaining temperature protection of these prescription drugs.

Manner and Means of the Conspiracy

The manner and means by which Newcomb and his coconspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following which occurred during the entire period of the conspiracy:

26. Newcomb and his coconspirators utilized drug packagers from the United Kingdom who obtained prescription drugs from Sierra Leone, Turkey, and other countries from outside the United States and shipped them at Newcomb and others' direction to physicians located in the United States.

Newcomb and others utilized exterior packaging that concealed the illegal nature of the drug shipments, such as sending packages falsely describing the contents as "medical samples," with little or no declared value. Newcomb and others paid these United Kingdom drug packagers for each drug shipment, directing payments from the United States based on the volume of foreign drug products sold to United States doctors.

Overt Acts

27. In furtherance of the conspiracy, and to achieve the objects thereof, defendant Newcomb and his co-conspirators, known and unknown, committed and caused to be committed the following overt acts, among others, in the Eastern Division of the Eastern District of Missouri and elsewhere:

a. While the agreement or understanding was in effect, defendant Newcomb, with the intent to defraud and mislead, on or about January 7, 2011, caused the introduction and delivery for introduction into interstate commerce quantities of adulterated prescription drugs, specifically a shipment of the drugs marketed in the United States as Neupogen® (1 300 mcg PFS 5 pack) and Rituxan® (2 100 mg 2 packs), from the United Kingdom to St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri.

All in violation of Title 18, United States Code, Section 371.

ADULTERATED DRUGS

COUNT 2

28. Paragraphs 1 through 23 of the General Allegations section of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

29. On or about October 16, 2010, within the Eastern Division of the Eastern District of Missouri, and the Southern Districts of Illinois and California, and elsewhere, defendant

SANDRA L. BEHE,

with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce quantities of prescription drugs from the United Kingdom to the Eastern District of Missouri and the Southern District of Illinois, specifically the prescription drug marketed in the United States as Rituxan® in two 100 milligram containers, that were adulterated. Specifically, each quantity of the drug shipments was adulterated because the methods of drug storage and shipment were not appropriate and did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug products, including maintaining temperature protection of these prescription drugs. All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B) and 18 U.S.C. § 2.

COUNT THREE

30. Paragraphs 1 through 23 of the General Allegations section of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

31. On or about December 10, 2010, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and in the Southern District of Illinois, and elsewhere,

ABID S. NISAR,

defendant herein, received in interstate commerce a quantity of the prescription drug marketed in the United States as Rituxan®, 100 milligram strength, imported from the United Kingdom to Granite City, Illinois and Florissant, Missouri, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that:

(a) the drug's labeling failed to bear adequate directions for use in that the drug's labeling was in the Turkish language, 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5, and;

(b) the drug came from a foreign drug establishment located in Switzerland and that drug was not annually listed with the FDA by that establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment. All in violation of 21 U.S.C. §§ 331(c), 333(a)(1), 352(f)(1)(o), 352(o), 360(j) and 18 U.S.C. § 2.

A TRUE BILL.

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FOREPERSON

RICHARD G. CALLAHAN
United States Attorney

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A.U.S.A. ANDREW J. LAY, #28542